IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

IN RE: SMITH & NEPHEW BIRMINGHAM HIP RESURFACING (BHR) HIP IMPLANT PRODUCTS LIABILITY LITIGATION	MDL No. 2775 Master Docket No. 1:17-md-2775 JUDGE CATHERINE C. BLAKE THIS DOCUMENT RELATES TO THE FOLLOWING CASES: *Paula and Jace Redick v. Smith & Nephew, Inc.*, No. 1:17-cv-00944 *Phyliss Mosca v. Smith & Nephew, Inc.*, No. 1:18-cv-03520

MEMORANDUM

Now pending are a host of motions in limine filed by Ms. Paula Redick ("Ms. Redick") and Ms. Phyliss Mosca ("Ms. Mosca") (collectively, "the plaintiffs") and by Smith & Nephew ("S&N") in this multidistrict litigation. The motions are fully briefed and oral argument was heard on April 28, 2021. Though it will not be possible to rule on many of the motions until specific evidence is proffered in the context of trial, the court endeavors herein to set appropriate boundaries on the admissibility of the challenged evidence. In this memorandum, the court will address twelve of the pending motions in limine; a subsequent memorandum will resolve the remaining motions.

LEGAL STANDARD

A motion in limine seeks to "exclude anticipated prejudicial evidence before the evidence is actually offered." *Luce v. United States*, 469 U.S. 38, 40 n.2 (1984). Such motions are "designed to narrow the evidentiary issues for trial and to eliminate unnecessary trial interruptions." *Louzon v. Ford Motor Co.*, 718 F.3d 556, 561 (6th Cir. 2013) (internal quotation marks omitted).

ANALYSIS

1. Dismissed Claims (ECF 2523)

S&N has moved to exclude evidence concerning claims that were already dismissed from the litigation. The court has previously ruled that several *claims* in this case are preempted; it has not, by contrast, ruled that any *evidence* is preempted. *See In re Smith & Nephew Birmingham Hip Resurfacing (BHR) Hip Implant Prods. Liab. Litig.*, 300 F. Supp. 3d 732, 743, 745, 747–48 (D. Md. 2018). Nor will it categorically do so today.

Without knowing specifically what evidence may be introduced or what arguments may be raised at trial, the court can offer only abstract guidance at this stage: evidence relevant only to dismissed claims will not be admitted; but evidence relevant to claims that remain in the case, even if also relevant to dismissed claims, may be admissible. A ruling on this motion is reserved. If such evidence is admitted, the parties may request appropriate limiting instructions as necessary.

2. Medical Device Reports (ECF 2526)

S&N moves to exclude evidence related to medical device reports ("MDRs"), otherwise known as adverse event reports ("AERs"). It argues these reports are not relevant to prove medical causation or comparative risk.

Under 21 C.F.R. § 803.10(c), medical device manufacturers are obligated to submit MDRs to the FDA. The FDA discloses those reports in its Manufacturer and User Facility Device Experience ("MAUDE") database, but notes that the database has limitations, "including the submission of incomplete, inaccurate, untimely, unverified, or biased data" and that establishing "a cause-and-effect relationship is especially difficult if circumstances surrounding the event have

not been verified or if the device in question has not been directly evaluated."[1] The regulations provide that submission of an MDR is "not necessarily an admission that the device . . . caused or contributed to the reportable event." 21 C.F.R. § 803.16.

While MDRs may be used to establish notice or knowledge or to suggest alternative causes, *see Berman v. Stryker Corp.*, No. 11 C 1309, 2013 WL 5348324, at *4 (N.D. Ill. Sept. 24, 2013) (collecting cases), they are generally not admissible as conclusive evidence of a product defect, *see id.*; *In re Bard IVC Filters Prods. Liab. Litig.*, No. MDL 15-02641-PHX DGC, 2018 WL 495607, at *5–6 (D. Ariz. Jan. 22, 2018), or as independent evidence of causation, *see McClain v. Metabolife, Int'l, Inc.*, 401 F.3d 1233, 1250 (11th Cir. 2005); *cf. In re Mirena IUD Prods. Liab. Litig.*, 202 F. Supp. 3d 304, 325 (S.D.N.Y. 2016) (adverse drug reaction reports not reliable evidence of causation); *Dunn v. Sandoz Pharms. Corp.*, 275 F. Supp. 2d 672, 682 (M.D.N.C. 2003) (noting case reports "are not scientific proof of causation"); *Rider v. Sandoz Pharms. Corp.*, 295 F.3d 1194, 1199 (11th Cir. 2002) (concluding that case reports by themselves were not reliable proof of causation).[2] On the other hand, a larger number of case reports with more detailed information might be a reliable source of expert opinion, *see Hollander v. Sandoz Pharms. Corp.*, 289 F.3d 1193, 1211 (10th Cir. 2002), and AERs may show notice or provide at least limited support for an expert's causation opinion, *see In re Tylenol (Acetaminophen) Mktg., Sales Practices and Prods. Liab. Litig.*, 181 F. Supp. 3d 278, 286–87 (E.D. Pa. 2016) (AERs for events similar to the one at issue in the litigation may be admissible to show notice); *In re Testosterone*

[1] FDA, "MAUDE – Manufacturer and User Facility Device Experience," available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm#disclaimer.

[2] Unpublished opinions are cited for the soundness of their reasoning and not for their precedential value.

Replacement Therapy Prods. Liab. Litig., MDL No. 2545, 2018 WL 2393161, at *3 (N.D. Ill. May 28, 2018) (denying motion to bar evidence of AERs).

Where it is unclear for what purpose an MDR or AER may be offered at trial, it is appropriate to "refuse[] to exclude such evidence in the motions stage of MDL litigation" because "there are simply too many factors" that might determine whether the evidence would be admissible. *Eghnayem v. Bos. Sci. Corp.*, No. 2:13-cv-07965, 2014 WL 5465741, at *7 (S.D.W. Va. Oct. 28, 2014) (internal quotation marks omitted).

In this case, the parties have not indicated which MDRs may be proffered, nor for what purpose. Accordingly, the court will not order any blanket exclusion of MDRs at this time. If evidence of MDRs is sought to be introduced at trial, the court may admit them subject to the preceding parameters. A ruling on this motion is reserved.

3. Other Litigation (ECF 2527)

S&N moves to exclude evidence concerning other litigation against it and other manufacturers and evidence concerning other individuals and their alleged injuries. It argues such evidence is irrelevant and would cause undue prejudice, confuse the jury, and result in unnecessary mini-trials.

Courts have concluded that evidence of other lawsuits, though it may be admissible to show notice or motive, often constitutes inadmissible hearsay and is likely to confuse a jury, waste time, and be prejudicial to the defendant. *See Sutphin v. Ethicon, Inc.*, No. 2:14-cv-001379, 2020 WL 5079170, at *6 (S.D. W. Va. Aug. 27, 2020); *Davenport v. Dunlop Tires N.A., Ltd.*, No. 1:15-cv-03752-JMC, 2018 WL 833606, at *2–3 (D.S.C. Feb. 13, 2018); *In re Tylenol* 181 F. Supp. 3d at 300. This is true especially when the evidence of lawsuits involves different devices or

manufacturers than the one involved in the present suit. *See Tyree v. Bos. Sci. Corp.*, No. 2:12-cv-08633, 2014 WL 5445769, at *7 (S.D. W. Va. Oct. 22, 2014).

When a party seeks to introduce evidence of other accidents or injuries arising from the same product, the party must demonstrate that the other accidents or injuries were substantially similar to the one at issue. *See Mirchandani v. Home Depot U.S.A., Inc.*, 470 F. Supp. 2d 579, 583 (D. Md. 2007). A court may exclude such evidence when its proponent fails to eliminate the material differences in the circumstances or nature of the alleged injury. *See Bryte ex rel. Bryte v. Am. Household, Inc.*, 429 F.3d 469, 479 (4th Cir. 2005). This requirement is somewhat relaxed, however, when evidence of other incidents, claims, and lawsuits is offered to show notice. *See Benedi v. McNeil-P.P.C., Inc.*, 66 F.3d 1378, 1385–86 (4th Cir. 1995); *see also Johnson v. Ford Motor Co.*, 988 F.2d 573, 579–80 (5th Cir. 1993) ("reasonable similarity" replaces "substantial similarity" when the evidence is offered to show notice). When evidence of prior claims or suits is offered to show notice, a court may (1) admit the evidence or (2) exclude the evidence under Rule 403 and instruct the jury that the defendant received notice. *See Benedi*, 66 F.3d at 1386.

A court may choose to deny as premature a motion which seeks a broad prohibition against the use of all prior incidents or lawsuits and fails to identify specific evidence that may be proffered at trial. *See A.K.W. by and through Stewart v. Riddell, Inc.*, No. 1:09CV703-HSO-JMR, 2012 WL 13018753, at *1 (S.D. Miss. Oct. 1, 2012) (denying motion as premature and requiring that, if plaintiff wishes to introduce such evidence, that plaintiff first lay a proper foundation outside the presence of the jury).

In this case, it is theoretically possible but practically unlikely that a proper basis can be shown to admit evidence of other lawsuits brought against other manufacturers, other lawsuits brought with respect to other devices, or even other lawsuits within this MDL. Even assuming

such evidence could be offered under an exception to the hearsay rule, it is almost certain to be of little or no probative value and is likely to pose a risk of unfair prejudice. If evidence of earlier lawsuits is offered to show notice—a permissible purpose—an instruction may be a sufficient substitute to achieve the proper effect without the risk of unfair prejudice. This analysis is not intended to exclude evidence, such as registry data, which documents the performance of other manufacturers' products as compared to the BHR; such evidence may be directly relevant to the plaintiffs' misrepresentation claims. A ruling on this motion is reserved.

4. Subsequent Remedial Measures (ECF 2528)

S&N argues that any evidence about subsequent remedial measures it took is barred by Federal Rule of Evidence 407 and 401. It contends that because Ms. Mosca's and Ms. Redick's injuries occurred due to implantation of the devices in 2010 and 2012, and because S&N's withdrawal of BHR components occurred later, in 2015, the act of withdrawal constitutes a subsequent remedial measure.[3]

Rule 407 provides that "[w]hen measures are taken that would have made an earlier injury or harm less likely to occur, evidence of the subsequent measures is not admissible to prove: negligence; culpable conduct; a defect in a product or its design; or a need for a warning or instruction." Fed. R. Evid. 407. Such evidence is admissible, however, for "another purpose, such as impeachment or—if disputed—proving ownership, control, or the feasibility of precautionary measures." *Id.* The rule is designed to "encourage[e] defendants to repair and improve their

[3] The plaintiffs argued in their papers that the evidence relating to actions taken by S&N in 2015 to contraindicate the BHR for women and to withdraw certain head sizes would be advanced only for impeachment purposes. Only in the course of oral argument did counsel cite to new cases and argue that this evidence did not even constitute a subsequent remedial measure. Though it is, at a minimum, unhelpful to advance novel arguments at such a late hour and after briefing has concluded, it appears—as explained herein—that there is merit to the plaintiffs' new position.

products and premises without fear that such actions will be used later against them in a lawsuit." *Werner v. Upjohn Co.*, 628 F.2d 848, 855 (4th Cir. 1980).

Evidence of a recall occurring after a plaintiff's accident is inadmissible. *See Chase v. Gen. Motors Corp.*, 856 F.2d 17, 20–22 (4th Cir. 1988). At the same time, evidence of a remedial measure which occurs *after* a plaintiff obtains a product but *before* the plaintiff's injuries arise is not barred by Rule 407. *See id.* (excluding evidence of a recall occurring subsequent to the plaintiff's accident, but declining to exclude evidence of a change in design occurring after the plaintiff purchased the product but before the plaintiff's injuries); *see also City of Richmond, Va. v. Madison Mgmt. Grp., Inc.*, 918 F.2d 438, 460 (4th Cir. 1990) (relevant "event" under former version of Rule 407 is bursting of a defective pipe rather than sale of a defective pipe). Indeed, as the Advisory Committee Notes from the 1997 Amendments to the Rule—which replaced the word "event" with the words "injury or harm"—state, "the rule applies only to changes made after the occurrence that produced the damages giving rise to the action." For example, in *Figueroa v. Boston Sci. Corp.*, a recall on a vaginal mesh device occurred four months before the discovery and diagnosis of the plaintiff's vaginal erosion and five months before the device was removed. No. 00 Civ. 7922(DC), 2003 WL 21488012, at *5 (S.D.N.Y. June 27, 2003). Acknowledging that some of the injury or harm likely occurred before the recall and some after, the court stated that "in any event the injury was not evident until [plaintiff] began to suffer vaginal bleeding in April 1999." *Id.* The court relied on *Chase*, 856 F.2d 17 (4th Cir. 1988), and overruled the Rule 407 objection. *Id. See also Cerqua v. Stryker Corp.*, No. 11 Civ. 9208(KBF), 2013 WL 1752284, at *15 n.5 (S.D.N.Y. Apr. 23, 2013) (recall was "likely admissible" where plaintiff had an implant in 2004, there was a recall in 2008, and the implant was removed in 2009); *Pusey v. Becton Dickinson & Co.*, 794 F. Supp. 2d 551, 561 (E.D. Pa. 2011) ("the critical juncture for determining

admissibility under Rule 407 is the occurrence of harm, not the event precipitating that harm") (citing *Sell v. Ingersoll-Rand Co.*, 136 F. App'x 545, 546 (3d Cir. 2005)).[4]

Additionally, evidence of subsequent remedial measures may be admissible for other purposes, such as for impeachment. *See Goehler v. Wal-Mart Stores, Inc.*, 229 F.3d 1142 (Table), 2020 WL 1161700, at *1 (4th Cir. 2000). In *Goehler*, defendant Wal-Mart first claimed that a soap dispenser was located over a sink such that any soap that fell from it would fall in the sink and not on the floor, where it might cause a person to slip. Even though Walmart eventually conceded that the dispenser had been moved, the original location of the dispenser—at the time of the injury—was disputed. Thus, the Fourth Circuit upheld the district court's admission of evidence of Walmart's change in position for impeachment purposes. *See id.* (and noting that since Walmart did not order the relocation of the soap dispenser for safety reasons, the admission of the evidence would not offend the policy rationale underlying Rule 407).

In this case, the plaintiffs' damages stem from the failure of their implants and their revision surgeries, and whether the remedial measures were "subsequent" is determined relative to those dates: for Ms. Redick, September 12, 2016; and for Ms. Mosca, February 20, 2018. Measured from those dates, S&N's actions preceded the plaintiff's injuries. The withdrawal of the R3 occurred on June 20, 2012; the voluntary withdrawal of the BHR for patients with femoral head sizes smaller than 46mm and the contraindication for female patients occurred on June 4, 2015. Thus, these are not subsequent remedial measures and Rule 407 poses no barrier to their admission. The motion is denied insofar as it seeks to exclude this evidence under Rule 407.

[4] The court did exclude evidence of post-implant measures in *Sutphin v. Ethicon, Inc*. *See* 2020 WL 5079170, at *6. But it does not appear that the plaintiffs presented the argument advanced here—that the failure of the implanted device, rather than the implant itself, is the injury or harm covered by Rule 407.

But that is not the end of the analysis. Evidence of withdrawal is a sharp sword which, without appropriate limiting instructions, may be wielded for impermissible purposes. Evidence of the withdrawal of certain head sizes of the BHR may be relevant to, for example, S&N's knowledge of risk, but may not be offered in support of preempted claims. For example, it may not be offered to suggest that S&N was under a duty to withdraw, or should have withdrawn, the device from the market. The court reserves ruling on whether this evidence is admissible pursuant to Rules 401 and 403. If such evidence is admitted, the court will seek the assistance of the parties to craft an appropriate limiting instruction with respect to this evidence.

As for evidence of the R3 withdrawal, the court is not persuaded this evidence will survive a Rule 403 challenge. This withdrawal says little about S&N's knowledge of BHR failure rates: the R3 is a different product and went to market under a separate regulatory approval. And, of course, this withdrawal may not be offered in support of any preempted claims. In sum, any relevance it has to the claims remaining in these BHR track cases is likely to be substantially outweighed by the risk of unfair prejudice and by the risk of confusing the issues. The motion is granted insofar as it seeks to exclude evidence of the R3 withdrawal.

5. Foreign Regulatory Actions (ECF 2530)

S&N moves to exclude evidence of actions or decisions made by foreign regulatory bodies regarding the BHR. It argues such decisions, a product of foreign law, are irrelevant and likely to confuse the jury.

In products liability litigation, some courts have found "evidence of foreign regulatory actions to be properly excluded as irrelevant or confusing." *In re Mirena IUD Prods. Liab. Litig.*, 169 F. Supp. 3d at 488 n.87 (and collecting cases); *see also In re Baycol Prods. Litig.*, 532 F. Supp. 2d 1029, 1054 (D. Minn. 2007) (excluding such evidence as confusing and collecting cases). One

court noted that to allow such evidence absent proper context would cause unfair prejudice to the opposing party by inviting the jury to "defer to the negative decisions of . . . foreign regulators"; and to provide the context necessary to eliminate that prejudice and enable a jury to properly evaluate evidence of foreign regulatory actions and foreign label changes would result in a series of mini-trials concerning the grounds for those actions, which would cause undue delay and confusion. *In re Seroquel Prods. Liab. Litig.*, 601 F. Supp. 2d 1313, 1318 (M.D. Fla. 2009).

However, such evidence may be admissible to show notice. *See In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, 499 F. Supp. 3d 505, 521 (S.D. Ohio 2020) (when evidence is put forward to demonstrate mere notice, the need for contextualization—and mini-trials—evaporates); *In re Tylenol*, 181 F. Supp. 3d at 306–07 (foreign labels on defendant's products warning of risk of severe liver damage are admissible evidence of defendant's knowledge of potential risks associated with its product); *see also In re Levaquin Prods. Liab. Litig.*, MDL No. 08-1943(JRT), 2010 WL 4676973, at *4–5 (D. Minn. Nov. 9, 2010) (presenting preliminary actions in Europe in conjunction with defendant's responses to show notice and motive is relevant, and not likely to cause confusion).

In this case, it is unclear which foreign regulatory actions or decisions may be proffered or for what purpose. If such evidence is sought to be introduced at trial, the court will evaluate its admissibility under the preceding framework and consider any appropriate limiting instructions or stipulations. A ruling on this motion is reserved.

6. Media Reports (ECF 2533)

S&N moves to exclude evidence of media reports about its company, the BHR, and any other products. It contends these reports are irrelevant, contain hearsay, and are prejudicial. It is true that media reports and newspaper articles, if offered for the truth of the matter asserted, are

hearsay. *See Crews v. Monarch Fire Protection Dist.*, 771 F.3d 1085, 1092 (8th Cir. 2014); *Greene v. Scott*, 637 F. App'x 749, 751-52 (4th Cir. 2016). In this case, no specific media reports have been identified in the papers. The court will evaluate the admissibility of such reports, if any are proffered, in the context of trial. A ruling on this motion is reserved.

7. Unrelated Medical Devices (ECF 2545)

S&N moves to exclude evidence relating to medical devices other than the BHR which were withdrawn, defective, or involved in other litigation. The court has already addressed the issue of other litigation in ruling on motion in limine number 5 (ECF 2527). The same rationale applies to withdrawals or defects in other devices: such evidence is almost certain to be of little or no probative value and is likely to confuse the jury or be unduly prejudicial. The motion is granted in part, and denied in part, insofar as this ruling is not intended to exclude evidence which establishes the performance of other manufacturers' products as compared to the BHR. Such evidence may be directly relevant to the plaintiffs' misrepresentation claims.

8. FDA Evidence (ECF 2556)

The plaintiffs move to exclude any discussion of the FDA and any argument about the regulatory status of the BHR. It argues that such evidence is not probative of any claims remaining in the case. The motion is denied insofar as it will likely not be possible to exclude all discussion of the FDA and the BHR's regulatory status, and the motion is granted insofar as what is admitted must be relevant to the claims remaining in the case. The court will seek the assistance of the parties in crafting an appropriate limiting instruction to inform the jury of the fact and significance of the PMA as well as to focus the jury's attention on events occurring after the PMA was granted.

9. Evidence Post-Dating Implant (ECF 2552) [Redick-Specific]

S&N has moved to exclude evidence concerning events that post-date Ms. Redick's implant surgery, which it argues are irrelevant to any remaining claims and would be confusing, misleading, and unfairly prejudicial. It is possible that documents or other evidence created after Ms. Redick's implant may shed light on S&N's knowledge of certain risks in the period prior to her implant. *See In re Tylenol*, 181 F. Supp. 3d at 300–01 (noting that communications occurring after a plaintiff's injuries occurred may demonstrate what the defendant knew about the risk of injury from the product prior to the plaintiff's injuries). Categorically excluding all evidence post-dating Ms. Redick's implant is therefore not appropriate. The court will address the relevance of specific evidence as it is offered at trial. A ruling on this motion is reserved.

10. Materials Not Seen by Ms. Redick or Her Surgeon (ECF 2553) [Redick-Specific]

S&N has moved to exclude evidence of marketing and other materials which neither Ms. Redick nor her surgeon ever saw, which it argues are irrelevant to any remaining claims and would be confusing and unfairly prejudicial. It is possible that documents which neither Ms. Redick nor her surgeon ever saw may help to prove that what they did see was in fact misleading. Categorically excluding all evidence of this nature is therefore not appropriate. The court will address the relevance of specific evidence as it is offered at trial. A ruling on this motion is reserved.

11. Information Smith & Nephew Was Not Required to Communicate (ECF 2554) [Redick-Specific]

S&N has moved to exclude evidence regarding information that it was not required to communicate under federal law, including evidence that Ms. Redick and her surgeon would have liked to have known additional information about the risks of the BHR. It argues this evidence is irrelevant and unfairly prejudicial. Though this evidence is potentially relevant to a preempted

claim, it is also relevant to Ms. Redick's surviving misrepresentation claim. Specifically, whether Dr. Bowling would have wanted to know about higher revision rates is relevant to whether the communications that he did receive were misleading by omission as well as to whether a disclosure would have made a difference in his decision to recommend the BHR. This motion is denied.

12. Collateral Source, Alternative Causation, and Tobacco Use (ECF 2557) [Redick-Specific]

Ms. Redick moves to exclude three categories of evidence: (1) evidence relating to payments made to or on behalf of Ms. Redick through any collateral sources; (2) evidence about any alternative causes for Ms. Redick's injuries; and (3) evidence of Ms. Redick's tobacco use.

First, relying on the collateral source rule, Ms. Redick seeks to exclude any evidence of payments made to her through Medicare or her private insurance. S&N does not intend to introduce any evidence concerning payment of Ms. Redick's medical expenses. (*See* ECF 2628, Opp'n at 1). Therefore, the motion is granted as to evidence of collateral source payments.

Second, Ms. Redick seeks to exclude any expert testimony which opines that Ms. Redick's revision was necessitated by a fracture. The court has addressed this issue in its May 17, 2021, Memorandum resolving the parties' *Daubert* motions. (*See* ECF 2717 at 27). Dr. Seyler has not offered his own differential diagnosis and therefore the motion is granted in part insofar as he may not testify that a fracture was the cause of Ms. Redick's revision. However, the motion is denied in part insofar as he may testify that a fracture should have been part of Dr. Shapiro's differential diagnosis.

Finally, Ms. Redick seeks to exclude evidence of her tobacco use. The court has also addressed this issue in its May 17, 2021, Memorandum. (*See id.*). Ms. Redick's history of smoking, given that Dr. Seyler does not even mention smoking in his explanation of the factors that must be

included in a differential diagnosis, is not relevant to challenging Dr. Shapiro's differential diagnosis. The motion is granted as to Ms. Redick's history of tobacco use.

CONCLUSION

For the reasons set forth herein, the court will grant in part and deny in part ECF 2545, 2556, and 2557; the court will grant in part, deny in part, and reserve in part ECF 2528; and the court will reserve ruling on ECF 2523, 2526, 2527, 2530, 2533, 2552, and 2553; and the court will deny ECF 2554. A separate Order follows.

June 11, 2021
Date

/s/
Catherine C. Blake
United States District Judge